

EXHIBIT 3

<p style="text-align: right;">Page 358</p> <p>1 Q. Fair enough.</p> <p>2 Doctor, I noticed, going</p> <p>3 back to your supplemental list of</p> <p>4 materials, Exhibit No. 4 --</p> <p>5 A. Okay.</p> <p>6 Q. -- that you were provided</p> <p>7 with reports of three of the plaintiffs</p> <p>8 other experts, Dr. Leffler, Tackett, and</p> <p>9 Lebwohl.</p> <p>10 A. Yes.</p> <p>11 Q. You were not provided,</p> <p>12 however, with a copy of Dr. Hutfless'</p> <p>13 report, were you, sir?</p> <p>14 A. Hutfless?</p> <p>15 Q. Hutfless, H-U-T-F-L-E-S-S?</p> <p>16 A. No.</p> <p>17 Q. Does that name even sound</p> <p>18 familiar?</p> <p>19 A. It does not.</p> <p>20 Q. I'll represent to you, sir,</p> <p>21 that she is an epidemiologist retained by</p> <p>22 the plaintiffs to offer opinions in this</p> <p>23 case.</p> <p>24 A. Okay.</p>	<p style="text-align: right;">Page 360</p> <p>1 patients had abdominal pain, but</p> <p>2 nothing serious.</p> <p>3 So we were kind of looking</p> <p>4 to see is there a broader -- part</p> <p>5 of what we were looking for was,</p> <p>6 is there a broader range of injury</p> <p>7 either caused by olmesartan or by</p> <p>8 other ARBs, and I would agree that</p> <p>9 we did not have a striking</p> <p>10 difference amongst any of the</p> <p>11 groups.</p> <p>12 BY MR. PARKER:</p> <p>13 Q. Those patients, the 20, came</p> <p>14 in with complaints of abdominal pain.</p> <p>15 A. Right.</p> <p>16 Q. With a history of taking</p> <p>17 olmesartan.</p> <p>18 A. Uh-hum.</p> <p>19 Q. What made them not</p> <p>20 sprue-like enteropathy patients?</p> <p>21 A. Well, several reasons: One</p> <p>22 is that none of the patients was</p> <p>23 dechallenged, ever, so all we would -- I</p> <p>24 think that there is a distinction to be</p>
<p style="text-align: right;">Page 359</p> <p>1 Q. I'll represent to you</p> <p>2 further, Doctor, that in discussing your</p> <p>3 paper, the one we talked about in 2015</p> <p>4 where you looked at 20 and 20, 20, 20,</p> <p>5 that she wrote that that paper does not</p> <p>6 contribute to evidence of causality or</p> <p>7 causation.</p> <p>8 Assuming I've made the</p> <p>9 representation accurately -- I believe I</p> <p>10 have -- do you agree or disagree with</p> <p>11 that conclusion of hers?</p> <p>12 MR. SLATER: Objection.</p> <p>13 THE WITNESS: I think that I</p> <p>14 would agree that that paper does</p> <p>15 not make a very significant impact</p> <p>16 to the story of causation; and,</p> <p>17 really, I would also point out</p> <p>18 that, you know, those were not</p> <p>19 olmesartan enteropathy patients</p> <p>20 that we were looking at. We were</p> <p>21 specifically trying to just</p> <p>22 approximate your typical GI clinic</p> <p>23 patient who maybe has something --</p> <p>24 they have a complaint, these</p>	<p style="text-align: right;">Page 361</p> <p>1 drawn here between the spectrum of the</p> <p>2 variability that can be seen in</p> <p>3 olmesartan enteropathy and the more</p> <p>4 common presentations.</p> <p>5 A very nonspecific, mild</p> <p>6 complaint like abdominal pain in a</p> <p>7 patient who happens to take olmesartan,</p> <p>8 is never taken off olmesartan, and never</p> <p>9 has any response or lack of response</p> <p>10 documented, that is not an olmesartan</p> <p>11 enteropathy patient.</p> <p>12 If those patients had -- if</p> <p>13 the gastroenterologists in those cases</p> <p>14 had decided to take them off olmesartan</p> <p>15 and it had had some impact on them, then</p> <p>16 we could talk about them potentially</p> <p>17 being olmesartan enteropathy patients.</p> <p>18 Q. So let me make sure I</p> <p>19 understand. These 20 patients were seen</p> <p>20 at Columbia; correct?</p> <p>21 A. Uh-hum.</p> <p>22 Q. They came in with abdominal</p> <p>23 pain to such a degree that they end up</p> <p>24 having an invasive procedure, an</p>

<p style="text-align: right;">Page 362</p> <p>1 endoscopy; correct?</p> <p>2 A. A common indication for a</p> <p>3 common procedure.</p> <p>4 Q. Where snips of their tissue</p> <p>5 were taken out and studied.</p> <p>6 A. Uh-hum.</p> <p>7 Q. With knowledge that they</p> <p>8 were taking olmesartan; correct?</p> <p>9 A. Uh-hum.</p> <p>10 Q. And the GIs at Columbia</p> <p>11 said, go on home, and they didn't tell</p> <p>12 them to stop taking olmesartan?</p> <p>13 A. To the best of my knowledge,</p> <p>14 they did not.</p> <p>15 Q. And how long was -- did this</p> <p>16 -- how long ago were these series of 20</p> <p>17 patients seen with abdominal pains,</p> <p>18 endoscopy results, and told -- knowing</p> <p>19 they had olmesartan -- just go on home</p> <p>20 and continue with your olmesartan?</p> <p>21 MR. SLATER: Objection; lack</p> <p>22 of foundation.</p> <p>23 THE WITNESS: Sorry. What</p> <p>24 was the question again?</p>	<p style="text-align: right;">Page 364</p> <p>1 ladies, we should go back and call these</p> <p>2 20 people and tell them maybe they should</p> <p>3 stop taking their olmesartan?</p> <p>4 MR. SLATER: With that same</p> <p>5 tone of voice, that -- that</p> <p>6 condescending we're a bunch of</p> <p>7 idiots voice that you're throwing</p> <p>8 out there, Bruce?</p> <p>9 MR. PARKER: I wouldn't say</p> <p>10 it was condescending. I would say</p> <p>11 I would be incredulous if I were</p> <p>12 at Columbia and realized they</p> <p>13 hadn't been told and given your</p> <p>14 views on this. Incredulous is the</p> <p>15 tone I was trying to convey.</p> <p>16 MR. SLATER: It's</p> <p>17 argumentative. We're almost</p> <p>18 there. Let's just take it easy.</p> <p>19 BY MR. PARKER:</p> <p>20 Q. Did you ever propose to your</p> <p>21 colleagues after you did this study that</p> <p>22 someone should make an effort and go back</p> <p>23 and talk to these people?</p> <p>24 MR. SLATER: Objection.</p>
<p style="text-align: right;">Page 363</p> <p>1 BY MR. PARKER:</p> <p>2 Q. Was this relatively -- I</p> <p>3 mean, your paper is 2015.</p> <p>4 A. Uh-hum.</p> <p>5 Q. When were these series of 20</p> <p>6 people seen at Columbia?</p> <p>7 A. Oh, from what years did we</p> <p>8 get the patients, do you mean?</p> <p>9 Q. Yes, sir.</p> <p>10 A. I'll have to check.</p> <p>11 Q. That's Exhibit 12 if that's</p> <p>12 helpful. Well, you can probably find it</p> <p>13 faster in your book.</p> <p>14 (Pause.)</p> <p>15 THE WITNESS: I don't think</p> <p>16 that we reported the years from</p> <p>17 which the biopsies were taken. I</p> <p>18 think, to the best of my</p> <p>19 recollection, it was maybe five or</p> <p>20 six years prior to the publication</p> <p>21 of this article, so --</p> <p>22 BY MR. PARKER:</p> <p>23 Q. And when you did your work,</p> <p>24 did you say to your colleagues, guys,</p>	<p style="text-align: right;">Page 365</p> <p>1 You can answer.</p> <p>2 THE WITNESS: Okay. We</p> <p>3 talked about whether we thought --</p> <p>4 whether we thought there was a</p> <p>5 reason to or not, and we decided</p> <p>6 that there wasn't and the reasons</p> <p>7 being, one, although there was a</p> <p>8 trend, it's a negative study. The</p> <p>9 P value is less than -- is more</p> <p>10 than .05, so we didn't have a</p> <p>11 definitive -- we couldn't assess</p> <p>12 causality or infer causality from</p> <p>13 something with only a trend and</p> <p>14 not a statistically significant</p> <p>15 difference --</p> <p>16 BY MR. PARKER:</p> <p>17 Q. But your views throughout</p> <p>18 today had been, if you had called back</p> <p>19 those 20 people still taking olmesartan,</p> <p>20 perhaps still having abdominal pain after</p> <p>21 all those years and you said stop taking</p> <p>22 olmesartan and they stopped taking it and</p> <p>23 the pain went away, that would prove</p> <p>24 causation. Right?</p>

<p style="text-align: right;">Page 366</p> <p>1 A. If a patient, whether 2 they're one of these 20 or not, had a 3 symptom and the only change that was made 4 was discontinuation of a medication and 5 that resulted in the resolution of their 6 symptom, then, yes, I would think that 7 that is some evidence that it was 8 causative. 9 Q. Let's turn to a different 10 area. 11 A. Okay. I'm just going to 12 grab some water. I'll be right back. 13 Q. Sure, sure. Take your time. 14 Doctor, I want to explore 15 another area and if this is getting into 16 the clinical realm and you don't feel 17 comfortable, tell me and I'll go on. 18 Is it your view, Doctor, 19 that a patient has to take olmesartan for 20 some period of time before any GI 21 symptoms that develop can be said to be 22 olmesartan enteropathy if they go away 23 when you stop taking the drug? 24 A. I would say that the</p>	<p style="text-align: right;">Page 368</p> <p>1 an increase in the symptoms? 2 A. Quickly. 3 Q. What does that mean? Hours 4 or days? 5 A. Hours to days. 6 Q. So in your understanding, a 7 -- well, strike that. Let me make a 8 foundation. 9 Is celiac also a 10 delayed-type hypersensitivity reaction? 11 MR. SLATER: Objection. 12 You can answer. 13 THE WITNESS: No. 14 BY MR. PARKER: 15 Q. What is your understanding 16 of the time course that the body needs to 17 mount an attack to something through a 18 delayed-type hypersensitivity reaction? 19 Is it hours or is it days? 20 A. I don't know. 21 Q. Now let's go back to my 22 question, Dr. Lagana. I want to go back 23 to what I started to ask you to make sure 24 I better understand your views on the</p>
<p style="text-align: right;">Page 367</p> <p>1 literature supports that there's a pretty 2 long lag time, on the order of months to 3 years, before olmesartan enteropathy 4 develops. 5 So I would say that maybe 6 not in all cases, but most of the cases 7 do involve a fairly long exposure before 8 the syndrome develops. 9 And I'll say that's also in 10 the primary context. The rechallenge 11 data is pretty notable in that once the 12 -- once the pump is primed for this 13 reaction, it does appear that people get 14 their relapses very quickly upon 15 reintroduction of olmesartan. 16 Q. Before I go on to my next 17 question, you just said something that 18 makes me think about this: When someone 19 is diagnosed with celiac disease and they 20 go on a gluten-free diet and have 21 improvement of their GI symptoms and then 22 resume gluten in their diet, what has 23 been your experience of the time course 24 in which they resume having symptoms or</p>	<p style="text-align: right;">Page 369</p> <p>1 time course that's needed to be on drug 2 before, if GI symptoms were to develop, 3 you might call them sprue-like 4 enteropathy. Okay? Let me try to flesh 5 that out for you. 6 A. Okay. 7 Q. If someone starts taking -- 8 well, let me ask a foundational question: 9 Is it your understanding that ARB drugs, 10 ACE drugs, other hypertension drugs, are 11 commonly associated with diarrhea? 12 A. Define "commonly." 13 Q. Well, do physicians who 14 prescribe that drug recognize and see in 15 their clinical practice that patients at 16 times within days of starting that drug 17 -- those drugs -- excuse me -- develop 18 diarrhea? 19 A. I would think so. I don't 20 see patients in an office, so I don't 21 have firsthand knowledge of that, but I 22 believe so. 23 Q. If someone starts taking 24 olmesartan and with two or three days</p>

<p style="text-align: right;">Page 370</p> <p>1 into taking the drug develop diarrhea, 2 and then after two days of diarrhea, they 3 stop the olmesartan and the diarrhea 4 stops, is that a case of sprue-like 5 enteropathy? 6 A. I wouldn't classify it that 7 way. I would classify it as an adverse 8 drug reaction, diarrhea, but I would not 9 think that fits criteria for sprue-like 10 enteropathy associated with olmesartan. 11 Q. Now let me go the other 12 extreme and let's say, after two years on 13 the drug, someone develops diarrhea and, 14 after two days, they just stop the drug 15 and the symptoms go away. Are those two 16 days of diarrhea sprue-like enteropathy? 17 A. They had two days of 18 diarrhea? 19 Q. Yeah, and then they stopped, 20 the diarrhea goes away. So both cases, 21 diarrhea for two days. One, it starts 22 two years after you start the drug, the 23 other one two days after you start the 24 drug.</p>	<p style="text-align: right;">Page 372</p> <p>1 hypothetical situation and those 2 are the only facts that exist in 3 this vacuum, I would say that that 4 question is not entirely -- it's 5 not entirely knowable. 6 BY MR. PARKER: 7 Q. And what is it about the 8 person who has been taking for two years, 9 develops diarrhea, stops the drug after 10 two days of diarrhea, and the diarrhea 11 goes away, what is unknowable about that 12 case the way you look at causation to 13 determine whether that's sprue-like 14 enteropathy? 15 MR. SLATER: Objection. 16 You can answer. 17 BY MR. PARKER: 18 Q. What else would you have to 19 know? 20 A. Okay. Let me think for a 21 moment before I answer you. 22 Q. Sure. 23 (Pause.) 24 THE WITNESS: So in your</p>
<p style="text-align: right;">Page 371</p> <p>1 A. Could you repeat the 2 question, please? I'm not sure I 3 understood. 4 Q. Sure. I'm trying get an 5 understanding. You said to me -- but if 6 I was wrong, correct me -- if someone 7 starts taking olmesartan and two or three 8 days into taking the drug, they develop 9 diarrhea and after two days they stop the 10 olmesartan and it goes away, you said, I 11 wouldn't characterize that as sprue-like 12 enteropathy. 13 A. Yes. 14 Q. Okay. 15 Now, if someone has been on 16 the drug for two years and then develops 17 diarrhea one day and, after two days of 18 diarrhea, stops taking olmesartan and the 19 diarrhea stops, does that now become a 20 case of sprue-like enteropathy? 21 MR. SLATER: Objection to 22 the form. 23 You can answer. 24 THE WITNESS: Well, in that</p>	<p style="text-align: right;">Page 373</p> <p>1 initial premise, two days would be 2 a very short period of time to 3 cause an organic change to the GI 4 tract, which is why I was pretty 5 comfortable excluding your initial 6 patient as an olmesartan 7 enteropathy patient. 8 In the second case, two 9 years is plenty of time for an 10 organic change to develop. The 11 most typical case of olmesartan 12 enteropathy that we've seen has 13 involved chronic diarrhea. That's 14 not all of them. That's an 15 example, but that's been defined 16 as 30 days or more of diarrhea. 17 Two days of diarrhea is an 18 extremely common scenario. The 19 person might have eaten something 20 bad. But if you showed me a 21 biopsy done while they were having 22 diarrhea, if it had histologic 23 features that were suggestive of 24 olmesartan enteropathy, and the</p>

<p style="text-align: right;">Page 374</p> <p>1 patient truly stopped having those</p> <p>2 features -- those symptoms after</p> <p>3 stopping the olmesartan, I would</p> <p>4 certainly consider the possibility</p> <p>5 that they might have had early</p> <p>6 olmesartan enteropathy.</p> <p>7 BY MR. PARKER:</p> <p>8 Q. It is your view, is it not,</p> <p>9 sir, that the only medical intervention</p> <p>10 that's needed in someone who you will say</p> <p>11 has sprue-like enteropathy is just stop</p> <p>12 taking olmesartan and you'll have</p> <p>13 complete recovery?</p> <p>14 MR. SLATER: Objection.</p> <p>15 You can answer.</p> <p>16 THE WITNESS: Okay.</p> <p>17 MR. SLATER: I'm not sure I</p> <p>18 understood it.</p> <p>19 THE WITNESS: Yeah, can you</p> <p>20 repeat that for me, please?</p> <p>21 MR. PARKER: Sure.</p> <p>22 THE WITNESS: Thank you.</p> <p>23 BY MR. PARKER:</p> <p>24 Q. Isn't it your view of</p>	<p style="text-align: right;">Page 376</p> <p>1 related to treatment or to</p> <p>2 diagnosis or both?</p> <p>3 MR. PARKER: Treatment. I</p> <p>4 said all you need to do is to tell</p> <p>5 them to stop taking olmesartan.</p> <p>6 THE WITNESS: Well, some of</p> <p>7 these patients come in with</p> <p>8 terrible dehydration and kidney</p> <p>9 damage, so if you don't rehydrate</p> <p>10 them, they'll die --</p> <p>11 MR. PARKER: My example was</p> <p>12 two days of diarrhea.</p> <p>13 THE WITNESS: Okay.</p> <p>14 MR. SLATER: Your question</p> <p>15 was different, though, the one you</p> <p>16 just asked there. So with all due</p> <p>17 respect to him, you actually asked</p> <p>18 a broader question.</p> <p>19 THE WITNESS: So, yes, I</p> <p>20 don't think that in every case</p> <p>21 simply holding olmesartan is the</p> <p>22 absolute only intervention that's</p> <p>23 required for those patients.</p> <p>24 BY MR. PARKER:</p>
<p style="text-align: right;">Page 375</p> <p>1 causation as expressed here that if</p> <p>2 somebody has developed sprue-like</p> <p>3 enteropathy associated with olmesartan,</p> <p>4 all you need do is to tell them to stop</p> <p>5 taking the olmesartan and they will have</p> <p>6 complete remission?</p> <p>7 A. No, I think that that's</p> <p>8 definitely mischaracterizing my</p> <p>9 statements on the topic. I will clarify,</p> <p>10 though.</p> <p>11 MR. SLATER: He's not asked</p> <p>12 you to, actually. If he wants you</p> <p>13 to, he'll ask you to.</p> <p>14 MR. PARKER: No, I wasn't</p> <p>15 going to because I got time</p> <p>16 problems.</p> <p>17 BY MR. PARKER:</p> <p>18 Q. Could you turn to reference</p> <p>19 --</p> <p>20 A. I would like to.</p> <p>21 MR. SLATER: Okay. I'm</p> <p>22 sorry.</p> <p>23 THE WITNESS: First off, I'd</p> <p>24 like to know, was that question</p>	<p style="text-align: right;">Page 377</p> <p>1 Q. Let me ask you to pull up</p> <p>2 the exhibit -- well, it's your 2016</p> <p>3 paper.</p> <p>4 A. The review article?</p> <p>5 Q. Yes, systematic review.</p> <p>6 A. Okay.</p> <p>7 Q. Exhibit 10.</p> <p>8 A. Okay.</p> <p>9 (Pause.)</p> <p>10 MR. PARKER: It might be</p> <p>11 easier to find it on the desk.</p> <p>12 THE WITNESS: Let's see. I</p> <p>13 got it.</p> <p>14 MR. PARKER: This is yours.</p> <p>15 That's not an exhibit.</p> <p>16 THE WITNESS: Okay. Thank</p> <p>17 you.</p> <p>18 BY MR. PARKER:</p> <p>19 Q. You got it?</p> <p>20 A. I got it.</p> <p>21 Q. Let's go to the last page of</p> <p>22 that article. Above references -- there</p> <p>23 you go -- and do you not say, "Cessation</p> <p>24 of olmesartan results in complete</p>

<p style="text-align: right;">Page 378</p> <p>1 resolution of both clinical and 2 histologic features"?</p> <p>3 A. I say that and that's true. 4 I don't believe I said that that happens 5 100 percent of the time completely. 6 Q. Well, you sure don't qualify 7 it in saying "in some patients," do you?</p> <p>8 MR. SLATER: Objection; 9 argumentative. Is there a 10 question?</p> <p>11 MR. PARKER: Yeah. 12 MR. SLATER: It's an 13 argumentative question. 14 MR. PARKER: You do not say 15 in this paper anywhere that only 16 some of the people who you take 17 off olmesartan will have complete 18 resolution of clinical and 19 histologic symptoms. 20 MR. SLATER: Objection; 21 foundation, argumentative. 22 THE WITNESS: In my 23 experience, the overwhelming 24 majority of patients who I have</p>	<p style="text-align: right;">Page 380</p> <p>1 had complete resolution of their 2 symptoms and feel great after 3 stopping olmesartan. 4 So what I said here, I stand 5 by. I think it's true. Does it 6 apply to every single patient? 7 Probably not. 8 MR. PARKER: Okay. 9 BY MR. PARKER: 10 Q. So go back to my example. 11 I'm still trying to understand what makes 12 a case of sprue-like enteropathy and what 13 doesn't. 14 If the patient has developed 15 diarrhea after starting the drug after 16 two days and has diarrhea for two days, 17 how is that case of diarrhea clinically 18 any different than the patient who's been 19 on the drug for two years, has two days 20 of diarrhea and stops the drug, and the 21 diarrhea goes away? 22 A. Well, I want to say object 23 to foundation, because two days -- two 24 days would be really not the typical</p>
<p style="text-align: right;">Page 379</p> <p>1 seen the biopsies for have had 2 complete resolution of their 3 histologic changes. 4 So I've seen patients who 5 had flat, small intestinal mucosa, 6 who had fibrosis, who had patterns 7 of injury that when I was in med 8 school were associated with high 9 mortality -- actually, collagenous 10 sprue was recently a pretty deadly 11 disease in a lot of patients -- 12 I've seen patients with that 13 histology go from that to looking 14 totally normal by biopsy, from 15 looking as if they just walked in 16 the street -- walked in off the 17 street feeling great, and that's 18 the vast majority of cases I've 19 seen. 20 I've seen very few cases 21 that had any residual damage; and 22 through discussion with my 23 clinical colleagues, most of the 24 patients that they've seen have</p>	<p style="text-align: right;">Page 381</p> <p>1 presentation of an olmesartan enteropathy 2 patient, so -- most of these patients 3 that we're talking about, we're not 4 talking about two days of diarrhea. 5 So let me say that I think 6 that the hypothetical situation is flawed 7 because two days is not really a 8 sufficient amount of time for us to think 9 about what we believe to be a fairly 10 uncommon entity when things like, you 11 know, eating a bad sandwich are common 12 and cause two days of diarrhea all the 13 time. 14 So I don't like the premise 15 of the question. 16 Q. Okay. You don't like the 17 premise of the question. 18 Doctor, nobody gets chronic 19 diarrhea overnight. Right? 20 MR. SLATER: Objection. 21 You can answer. 22 THE WITNESS: Right. 23 Chronic diarrhea is defined as 24 four weeks.</p>

<p style="text-align: right;">Page 382</p> <p>1 BY MR. PARKER:</p> <p>2 Q. Right. So in your view of</p> <p>3 causality, if someone has been on</p> <p>4 olmesartan, develops diarrhea, and for</p> <p>5 any reason, their spouse, their doctor,</p> <p>6 whatever, or they decide to stop taking</p> <p>7 olmesartan, you would expect them to have</p> <p>8 complete relief.</p> <p>9 MR. SLATER: Objection.</p> <p>10 THE WITNESS: Can you repeat</p> <p>11 that? That was a little</p> <p>12 confusing.</p> <p>13 BY MR. PARKER:</p> <p>14 Q. Yeah. If somebody after two</p> <p>15 years of olmesartan use develops diarrhea</p> <p>16 and, for whatever reason, their own sense</p> <p>17 or suggestion of a doctor that may have</p> <p>18 just read one of your papers, says stop</p> <p>19 using olmesartan, and the diarrhea gets</p> <p>20 better, that's what you would expect them</p> <p>21 to do, they would get better; correct?</p> <p>22 MR. SLATER: Objection.</p> <p>23 You can answer.</p> <p>24 THE WITNESS: I would only</p>	<p style="text-align: right;">Page 384</p> <p>1 the sun for six hours, you ate it, most</p> <p>2 likely you had food poisoning. So</p> <p>3 there's a clinical judgment that goes</p> <p>4 into this.</p> <p>5 Now, if I was that patient's</p> <p>6 doctor and the patient had just two days</p> <p>7 of diarrhea and I really -- really wanted</p> <p>8 to know if that person had olmesartan</p> <p>9 enteropathy or not, in that case,</p> <p>10 considering that the person does not fit</p> <p>11 the typical clinical description of</p> <p>12 olmesartan enteropathy, which is chronic</p> <p>13 diarrhea, I would suggest a rechallenge.</p> <p>14 Q. Okay. But, Doctor, the only</p> <p>15 reason they don't fit the picture is</p> <p>16 because there has been somebody or</p> <p>17 decisions have been made to intervene and</p> <p>18 stop the olmesartan; correct?</p> <p>19 MR. SLATER: Objection.</p> <p>20 You can answer. The</p> <p>21 hypothetical's migrating, but you</p> <p>22 can answer.</p> <p>23 THE WITNESS: There are</p> <p>24 degrees of certainty for any</p>
<p style="text-align: right;">Page 383</p> <p>1 expect that if they had olmesartan</p> <p>2 enteropathy. If they ate bad egg</p> <p>3 salad, no -- I would still expect</p> <p>4 them to get better, but it</p> <p>5 wouldn't have anything to do with</p> <p>6 the olmesartan.</p> <p>7 BY MR. PARKER:</p> <p>8 Q. And how would you then know</p> <p>9 that -- if they stopped taking it, after</p> <p>10 two days the diarrhea goes away, isn't</p> <p>11 that dechallenge?</p> <p>12 A. That is dechallenge. But</p> <p>13 then there could be rechallenge. If the</p> <p>14 person said I was at a party and there</p> <p>15 was some egg salad sitting around for six</p> <p>16 hours and I ate that, and if I was that</p> <p>17 person's doctor -- and, of course, this</p> <p>18 is a clinical judgment made by the</p> <p>19 doctor, not a decision -- not a</p> <p>20 hypothetical situation made in the vacuum</p> <p>21 of a boardroom. This is a -- if we're</p> <p>22 talking about a real-world scenario, that</p> <p>23 doctor would probably say, you were at a</p> <p>24 party in Florida, the egg salad was in</p>	<p style="text-align: right;">Page 385</p> <p>1 diagnosis that one makes or</p> <p>2 doesn't make. Even when you</p> <p>3 exclude something and you say it's</p> <p>4 not this, that doesn't usually</p> <p>5 mean that you're 100 percent. It</p> <p>6 means you think it's unlikely.</p> <p>7 So if a patient had just two</p> <p>8 days of diarrhea and then</p> <p>9 discontinued olmesartan and felt</p> <p>10 better, I would not feel like the</p> <p>11 patient definitely had olmesartan</p> <p>12 enteropathy and I would not feel</p> <p>13 that the patient definitely did</p> <p>14 not.</p> <p>15 I would consider the</p> <p>16 patient's clinical state and the</p> <p>17 rest of the patient's scenario and</p> <p>18 if it were important for the</p> <p>19 patient to be able to take</p> <p>20 olmesartan, I would rechallenge</p> <p>21 that patient and test it.</p> <p>22 MR. PARKER: I got a few</p> <p>23 minutes before I want to stop and</p> <p>24 give myself some time after Mr.</p>

<p style="text-align: right;">Page 386</p> <p>1 Slater does his questioning.</p> <p>2 BY MR. PARKER:</p> <p>3 Q. Doctor, we were told by</p> <p>4 letter -- I don't see it in your</p> <p>5 references -- that you were provided with</p> <p>6 some of the reports of some of the</p> <p>7 defense experts?</p> <p>8 A. Yes, I was.</p> <p>9 Q. And by memory, I recall</p> <p>10 Turner and Wilson being the two. Were</p> <p>11 there any others?</p> <p>12 A. There was one other that I</p> <p>13 glanced at. Can you mention some of</p> <p>14 them?</p> <p>15 Q. Well, there would be a</p> <p>16 Risch, a Hanson, a Popp, and a Mann.</p> <p>17 Those are the other four plus Turner and</p> <p>18 Wilson.</p> <p>19 A. Those other names don't</p> <p>20 sound familiar. Turner and Wilson, I</p> <p>21 definitely have read.</p> <p>22 Q. Do you know Dr. Turner?</p> <p>23 A. We've never met. I've heard</p> <p>24 of him.</p>	<p style="text-align: right;">Page 388</p> <p>1 THE WITNESS: Well, at the</p> <p>2 bottom of page 3, this report</p> <p>3 draws on the cases described in</p> <p>4 the Cartee paper and does directly</p> <p>5 infer that they're the same cases</p> <p>6 in Rubio-Tapia 2012, and I think</p> <p>7 that that's a baseless connection.</p> <p>8 (Pause.)</p> <p>9 THE WITNESS: He says all --</p> <p>10 on page 5, the first paragraph</p> <p>11 towards the end, he says all</p> <p>12 available data suggests that</p> <p>13 seronegative celiac disease</p> <p>14 remains a far more common</p> <p>15 diagnosis than ditto even in a --</p> <p>16 which is his phraseology for</p> <p>17 olmesartan enteropathy -- even in</p> <p>18 a tertiary referral center and so</p> <p>19 that he references DeGaetani. I</p> <p>20 would say "far more" is an</p> <p>21 overstatement of the data.</p> <p>22 (Pause.)</p> <p>23 THE WITNESS: Many of his</p> <p>24 opinions seem to be -- seem to</p>
<p style="text-align: right;">Page 387</p> <p>1 Q. Are you familiar with the</p> <p>2 work that he has done in the field of</p> <p>3 pathology?</p> <p>4 A. I don't have much -- I have</p> <p>5 heard his name. I know he's a respected</p> <p>6 guy. I don't know him or the specifics</p> <p>7 of his work in any great depth.</p> <p>8 Q. Early on in response to one</p> <p>9 of my questions, you said, well, I had</p> <p>10 read these reports and I think it was in</p> <p>11 the context of you telling me you weren't</p> <p>12 sure that there was anybody -- or you</p> <p>13 weren't aware that anybody disagreed with</p> <p>14 causation until you started reading some</p> <p>15 of these reports. And they didn't, of</p> <p>16 course, change your mind.</p> <p>17 When you read Dr. Turner's</p> <p>18 report, was there anything factual -- I'm</p> <p>19 not asking about his opinions, but</p> <p>20 factual -- that you can tell me he's just</p> <p>21 wrong about?</p> <p>22 A. Let me take a look.</p> <p>23 Q. Please.</p> <p>24 (Pause.)</p>	<p style="text-align: right;">Page 389</p> <p>1 boil down to, there are variations</p> <p>2 in presentation, therefore, this</p> <p>3 doesn't exist. It's either three</p> <p>4 things or it's nothing, and I find</p> <p>5 that to be a recurring theme in</p> <p>6 this report and I also find it to</p> <p>7 be a terribly unconvincing theme.</p> <p>8 I think that if you look at</p> <p>9 any GI inflammatory disease,</p> <p>10 celiac disease, for instance, the</p> <p>11 classical Marsh grading allows for</p> <p>12 six different manifestations of</p> <p>13 the disease and that's not even</p> <p>14 counting complications.</p> <p>15 So I think a frequent theme</p> <p>16 here is variability equals</p> <p>17 nonexistence and I find that to be</p> <p>18 a specious argument --</p> <p>19 BY MR. PARKER:</p> <p>20 Q. Okay. But I was asking</p> <p>21 about facts.</p> <p>22 A. Okay.</p> <p>23 (Pause.)</p> <p>24 THE WITNESS: So I notice</p>

<p style="text-align: right;">Page 390</p> <p>1 that I have left two sticky -- I</p> <p>2 have two sticky notes on here. I</p> <p>3 think -- do those need to be --</p> <p>4 MR. PARKER: I'm not asking</p> <p>5 you to give it to me. I'm just --</p> <p>6 THE WITNESS: All right. I</p> <p>7 just want to -- you know, I don't</p> <p>8 want to be holding anything back</p> <p>9 that's not supposed to be --</p> <p>10 MR. PARKER: I appreciate</p> <p>11 your candor, but, no, I got only</p> <p>12 ten minutes left, Doctor, so I</p> <p>13 want to save myself five, if you</p> <p>14 could wrap it up in five minutes.</p> <p>15 THE WITNESS: I will do my</p> <p>16 best.</p> <p>17 (Pause.)</p> <p>18 THE WITNESS: Well, clearly,</p> <p>19 I think he mischaracterizes my</p> <p>20 2015 study quite -- quite badly.</p> <p>21 Talking about the P value we</p> <p>22 published of 0.34, that's a very</p> <p>23 unfair characterization, because</p> <p>24 we published that there was a</p>	<p style="text-align: right;">Page 392</p> <p>1 have taken place in the</p> <p>2 literature, not only in</p> <p>3 Rubio-Tapia, but also in</p> <p>4 subsequent reports.</p> <p>5 BY MR. PARKER:</p> <p>6 Q. Rubio-Tapia didn't have any</p> <p>7 rechallenge.</p> <p>8 A. It didn't have controlled</p> <p>9 rechallenge, meaning that it didn't have</p> <p>10 planned rechallenge, but there were</p> <p>11 rechallenges.</p> <p>12 Q. The anecdotal report, you're</p> <p>13 talking about the two patients.</p> <p>14 MR. SLATER: Objection;</p> <p>15 mischaracterization, lack of</p> <p>16 foundation.</p> <p>17 THE WITNESS: I'm talking</p> <p>18 about the rechallenges which were</p> <p>19 not controlled, which were</p> <p>20 described in Rubio-Tapia.</p> <p>21 BY MR. PARKER:</p> <p>22 Q. Okay. 2012 paper.</p> <p>23 A. 2012.</p> <p>24 Q. Okay.</p>
<p style="text-align: right;">Page 391</p> <p>1 trend towards significance in the</p> <p>2 olmesartan-exposed patients, as we</p> <p>3 said, a P value of .1, and we</p> <p>4 compared that to the P value of</p> <p>5 other -- of other ARBs or compared</p> <p>6 to matched controls for them of --</p> <p>7 and that was .34.</p> <p>8 So we were saying that</p> <p>9 there's a trend towards difference</p> <p>10 in the olmesartan users and no</p> <p>11 trend towards difference in the</p> <p>12 other ARB users.</p> <p>13 So the way that Dr. Turner</p> <p>14 has picked this out and</p> <p>15 highlighted this in his report,</p> <p>16 though factually -- the facts are</p> <p>17 true, we did report that one group</p> <p>18 had P equals .34, it's a very</p> <p>19 unfair characterization of what we</p> <p>20 published.</p> <p>21 (Pause.)</p> <p>22 THE WITNESS: I think on the</p> <p>23 top of page 9, he also really</p> <p>24 whitewashes the rechallenges that</p>	<p style="text-align: right;">Page 393</p> <p>1 A. And there are -- if we're</p> <p>2 getting on the topic of are there other</p> <p>3 rechallenges, there are rechallenges in</p> <p>4 the FDA. There are rechallenges in</p> <p>5 Theophile. There are rechallenges in</p> <p>6 Ianiro, all of which are positive.</p> <p>7 And there are more</p> <p>8 rechallenges; and if we want to contest</p> <p>9 this point, I would be happy to go</p> <p>10 through this and point to every positive</p> <p>11 rechallenge.</p> <p>12 Q. I was only following up on</p> <p>13 your comment about Rubio-Tapia.</p> <p>14 A. Okay. I want to make the</p> <p>15 point that there are quite a few positive</p> <p>16 rechallenges in the literature and if you</p> <p>17 want to go into that in more depth, I'm</p> <p>18 willing to.</p> <p>19 Q. I don't want that. I just</p> <p>20 want to hear what other -- if there were</p> <p>21 anything else in Turner's report that you</p> <p>22 believe to be factually incorrect.</p> <p>23 A. Okay. Well, I'm on the last</p> <p>24 page.</p>

<p style="text-align: right;">Page 394</p> <p>1 Q. Okay. Good news.</p> <p>2 A. I think I would leave off</p> <p>3 with Turner's report by saying, I</p> <p>4 disagree with his conclusions. I think</p> <p>5 many of them are unfair and unfounded and</p> <p>6 I disagree.</p> <p>7 MR. PARKER: Okay. Thank</p> <p>8 you. I'll save whatever couple</p> <p>9 minutes I have until after Mr.</p> <p>10 Slater's finished.</p> <p>11 MR. SLATER: On my count,</p> <p>12 that's seven minutes. We're going</p> <p>13 to take a break. I have to</p> <p>14 organize my notes, so we'll take a</p> <p>15 few.</p> <p>16 (A recess was taken from</p> <p>17 6:32 p.m. to 7:05 p.m.)</p> <p>18 - - -</p> <p>19 EXAMINATION</p> <p>20 - - -</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Doctor, you were asked by</p> <p>23 counsel before the break about your</p> <p>24 comments in terms of your -- so the</p>	<p style="text-align: right;">Page 396</p> <p>1 Q. What would need to have been</p> <p>2 disclosed per the standards for</p> <p>3 disclosure of a conflict for that</p> <p>4 journal?</p> <p>5 A. Paid testimony.</p> <p>6 Q. Paid expert testimony?</p> <p>7 A. Yes, paid expert testimony.</p> <p>8 Q. Had you given any paid</p> <p>9 expert testimony in connection with</p> <p>10 olmesartan at the time this was</p> <p>11 published?</p> <p>12 A. I had not.</p> <p>13 Q. Did any of the authors</p> <p>14 disclose any sort of a conflict related</p> <p>15 to being a consultant to any of the</p> <p>16 people that may be involved with</p> <p>17 olmesartan? For example, if any of them</p> <p>18 were consulting for Daiichi at the time</p> <p>19 it was published, did anybody disclose</p> <p>20 anything like that?</p> <p>21 A. No.</p> <p>22 Q. In that article, reference 9</p> <p>23 -- and we're talking about the Burbure</p> <p>24 article. Right? B-U-R-B-U-R-E. Right?</p>
<p style="text-align: right;">Page 395</p> <p>1 criticisms you had of some factual</p> <p>2 statements, some opinions from Dr.</p> <p>3 Turner's report a few moments ago.</p> <p>4 Right?</p> <p>5 A. I was asked about that,</p> <p>6 yeah.</p> <p>7 Q. If you were asked the same</p> <p>8 question and you were asked to go through</p> <p>9 Dr. Wilson's report, could you do the</p> <p>10 same thing and go through this as well in</p> <p>11 detail if he asked you do that?</p> <p>12 A. Yes.</p> <p>13 Q. Now, you were asked some</p> <p>14 questions about your 2016 article, your</p> <p>15 systematic review and whether you</p> <p>16 disclosed a, quote, unquote, conflict of</p> <p>17 interest.</p> <p>18 Do you remember counsel</p> <p>19 asked you about that?</p> <p>20 A. I do.</p> <p>21 Q. Did you have an opportunity</p> <p>22 to look at the standards for what would</p> <p>23 need to be disclosed for that journal?</p> <p>24 A. I did.</p>	<p style="text-align: right;">Page 397</p> <p>1 A. Uh-hum.</p> <p>2 Q. Okay.</p> <p>3 Reference 9 in that article</p> <p>4 is what?</p> <p>5 A. Reference 9 in that article</p> <p>6 is the Rubio-Tapia/Murray article on</p> <p>7 collagenous sprue from 2010.</p> <p>8 Q. I might have misspoken. Let</p> <p>9 me ask you a different question: What is</p> <p>10 reference 24?</p> <p>11 A. Okay. Basson.</p> <p>12 Q. Were you fully aware of the</p> <p>13 Basson article when you wrote this report</p> <p>14 in this case?</p> <p>15 A. Yes.</p> <p>16 Q. It wasn't listed on your</p> <p>17 reliance list. Was that an oversight?</p> <p>18 A. Yes.</p> <p>19 Q. Okay.</p> <p>20 Now, in this article,</p> <p>21 Burbure, on page 132, there's a reference</p> <p>22 under section 5 to establishing, quote,</p> <p>23 the diagnosis of olmesartan-induced</p> <p>24 injury. Okay?</p>

<p style="text-align: right;">Page 398</p> <p>1 A. Okay.</p> <p>2 Q. What does that mean,</p> <p>3 olmesartan-induced injury, in that</p> <p>4 article?</p> <p>5 A. Well, that reflects the</p> <p>6 belief that we have -- that olmesartan is</p> <p>7 causing injury in this subset of</p> <p>8 patients; and as I think I said</p> <p>9 previously, until I read defense expert</p> <p>10 reports, I had not heard any controversy</p> <p>11 on that point either from my colleagues</p> <p>12 or investigators at other centers.</p> <p>13 We have seen it in practice.</p> <p>14 We believe it. And that term is meant to</p> <p>15 plainly say it.</p> <p>16 Q. There was some question of</p> <p>17 you, very early in the day today, and</p> <p>18 there was questioning about, quote,</p> <p>19 unquote, confused histopathology, about</p> <p>20 being confused with that.</p> <p>21 Was that meant to suggest</p> <p>22 that somebody's making a mistake in terms</p> <p>23 of looking at histopathology as between</p> <p>24 those various entities?</p>	<p style="text-align: right;">Page 400</p> <p>1 that can histologically resemble</p> <p>2 olmesartan enteropathy, but that would be</p> <p>3 in a patient who had a bone marrow</p> <p>4 transplant. So knowing the whole</p> <p>5 clinical picture is vital.</p> <p>6 Q. Okay.</p> <p>7 I'm going to ask you now</p> <p>8 about the Rubio-Tapia article from 2012</p> <p>9 and I actually have the page here to save</p> <p>10 time.</p> <p>11 A. Okay.</p> <p>12 Q. It's okay.</p> <p>13 I'm looking at page 737 of</p> <p>14 the article, table 3, and what is the</p> <p>15 title of table 3?</p> <p>16 A. "Clinical features of</p> <p>17 sprue-like enteropathy associated with</p> <p>18 olmesartan."</p> <p>19 Q. Does it say "the" clinical</p> <p>20 features of sprue-like enteropathy? Is</p> <p>21 the word "the" there in that sentence?</p> <p>22 A. No.</p> <p>23 Q. Your reading of this table,</p> <p>24 is that meant to be an exhaustive list of</p>
<p style="text-align: right;">Page 399</p> <p>1 A. On the differential</p> <p>2 diagnosis?</p> <p>3 Q. Right.</p> <p>4 A. What I was trying to say is</p> <p>5 that some of those entities</p> <p>6 histologically can have similarities and</p> <p>7 I wasn't -- I wasn't trying to say that</p> <p>8 the pathologist would make a mistake by</p> <p>9 calling one the other. I was saying that</p> <p>10 there is histologic overlap amongst those</p> <p>11 entities.</p> <p>12 Q. And what's the importance of</p> <p>13 clinical correlation in that context?</p> <p>14 A. Well, clinical correlation</p> <p>15 is vital. Certainly if one is</p> <p>16 considering the diagnosis of olmesartan</p> <p>17 enteropathy, knowing that the patient was</p> <p>18 exposed to olmesartan would be pretty</p> <p>19 important.</p> <p>20 And there are other entities</p> <p>21 on the differential that would need to be</p> <p>22 considered that also require clinical</p> <p>23 correlation. For instance, if we were</p> <p>24 talking about graft versus host disease,</p>	<p style="text-align: right;">Page 401</p> <p>1 clinical features?</p> <p>2 A. No. I think that these are</p> <p>3 some features, common examples of what</p> <p>4 they saw in their first 22 patients, and</p> <p>5 I certainly wouldn't take this to be</p> <p>6 exhaustive or exclusionary of other</p> <p>7 findings.</p> <p>8 Q. The last section of that</p> <p>9 table says, "evidence of clinical and</p> <p>10 histologic improvement after suspension</p> <p>11 of olmesartan."</p> <p>12 What's the significance of</p> <p>13 the use of the word "improvement" there?</p> <p>14 A. Well, we've discussed this a</p> <p>15 few times today, whether improvement or</p> <p>16 resolution is necessary.</p> <p>17 I think this is</p> <p>18 acknowledging that improvement is really,</p> <p>19 well, in some cases, the best you can</p> <p>20 hope for. Certainly you'd like to see</p> <p>21 complete resolution. You've got a sick</p> <p>22 patient.</p> <p>23 But if you have improvement,</p> <p>24 that would be strong evidence of</p>

<p style="text-align: right;">Page 402</p> <p>1 causation, if that was the only thing 2 that changed.</p> <p>3 Q. You were asked by counsel a 4 few minutes ago about a hypothetical 5 where he said a patient is assumed to 6 have taken olmesartan for two years and 7 then after two years develops diarrhea 8 that lasts for two days and, after those 9 two days are up, the person stops taking 10 olmesartan for whatever reason.</p> <p>11 First question on that 12 person, would the differential diagnosis 13 -- if you were looking back 14 retrospectively to try to figure out what 15 had caused the diarrhea, would the 16 differential include olmesartan 17 enteropathy? Yes or no.</p> <p>18 A. Yes.</p> <p>19 Q. If you wanted to be more 20 sure of that at the time, when the person 21 stopped taking the drug and then got 22 better, would an endoscopy provide 23 information if the person had had an 24 endoscopy at that time?</p>	<p style="text-align: right;">Page 404</p> <p>1 diagnosis of malabsorption) are strong 2 arguments in favor of causality."</p> <p>3 Is that statement of any 4 significance to you?</p> <p>5 A. Well, yeah, I think it's a 6 -- it's a strong statement. They're 7 applying the Bradford Hill criteria 8 there, or at least some of them, and I 9 think that -- well, they've said it quite 10 plainly, that their findings are strong 11 evidence in favor of causality, and I 12 agree with that.</p> <p>13 Q. You mentioned --</p> <p>14 A. And by the way, if I could 15 just mention another thing about this 16 study --</p> <p>17 Q. Sure.</p> <p>18 A. -- which I don't think that 19 we got to too specifically, when you look 20 at the strength of the association, the 21 relative risk of 5 or 10 as is seen after 22 two years of therapy on olmesartan, 23 that's a very high relative risk.</p> <p>24 Q. And why is that significant?</p>
<p style="text-align: right;">Page 403</p> <p>1 A. It certainly could, yeah.</p> <p>2 Q. Could potentially.</p> <p>3 A. Uh-hum.</p> <p>4 Q. Would a rechallenger 5 potentially provide important information 6 as well if someone wanted to be sure -- 7 you know, you got better after two days. 8 Would giving the drug to the person again 9 and seeing whether it recurs, would that 10 be helpful information?</p> <p>11 A. It would.</p> <p>12 Q. And depending on the 13 findings, that would be clinical 14 information that would be factored into 15 an ultimate diagnosis?</p> <p>16 A. It would.</p> <p>17 Q. Now, looking at the Basson 18 article -- I'm just going to turn to it 19 real quick -- and looking at page 5 of 20 the article, and there's a statement here 21 on the top left, "The strength of the 22 association and the consistency with 23 reported cases (including the long lag 24 time between initiation of olmesartan and</p>	<p style="text-align: right;">Page 405</p> <p>1 A. Well, again, getting back to 2 the -- if we think about the Bradford 3 Hill criteria, the strength of the 4 association, the fact that there's a 5 tenfold increased risk is strong.</p> <p>6 Q. And, you know, you've 7 mentioned the Bradford Hill criteria. 8 Counsel had asked you if it was 9 specifically mentioned in your report. 10 You didn't actually name that criteria; 11 correct?</p> <p>12 A. That's true.</p> <p>13 Q. Were you fully familiar with 14 that criteria when you did your report?</p> <p>15 A. Yeah --</p> <p>16 MR. PARKER: Objection.</p> <p>17 MR. SLATER: Let me ask the 18 question again.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Were you familiar with the 21 Bradford Hill criteria when you did your 22 analysis and wrote your report in this 23 case?</p> <p>24 A. Yeah.</p>

<p style="text-align: right;">Page 406</p> <p>1 Q. Okay.</p> <p>2 Even though it was not</p> <p>3 named, did you take into account the</p> <p>4 factors in the Bradford Hill criteria in</p> <p>5 doing your analysis of the available</p> <p>6 information that you relied on in forming</p> <p>7 your opinion?</p> <p>8 MR. PARKER: Objection.</p> <p>9 MR. SLATER: You can answer.</p> <p>10 THE WITNESS: Okay. I think</p> <p>11 that those factors are fundamental</p> <p>12 to how people in medicine think</p> <p>13 about medical science, and</p> <p>14 certainly I did think about them</p> <p>15 and I did address them, although</p> <p>16 not in the context of listing the</p> <p>17 criteria point -- on a</p> <p>18 point-by-point basis. But, yeah,</p> <p>19 I did think about them and I did</p> <p>20 try to incorporate them.</p> <p>21 MR. SLATER: And I'm just,</p> <p>22 for the record, going to give you</p> <p>23 a list of the Bradford Hill</p> <p>24 criteria.</p>	<p style="text-align: right;">Page 408</p> <p>1 putting that all together, did you</p> <p>2 incorporate analysis of those factors</p> <p>3 that was implicit into your analysis of</p> <p>4 this material?</p> <p>5 MR. PARKER: Objection.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Coming back to the Basson</p> <p>9 article, towards the end at the bottom of</p> <p>10 page 5, there's a statement that says,</p> <p>11 "Patients treated with olmesartan should</p> <p>12 be informed about the risk of this</p> <p>13 complication, and should be advised to</p> <p>14 seek medical attention if they experience</p> <p>15 gastrointestinal symptoms. This</p> <p>16 information should also be widely</p> <p>17 delivered to physicians of all</p> <p>18 disciplines, particularly to</p> <p>19 gastroenterologists who are faced to this</p> <p>20 new category of patients."</p> <p>21 In the context of a question</p> <p>22 of whether there's -- whether the authors</p> <p>23 in this article had a viewpoint on</p> <p>24 causation, is that statement I just read</p>
<p style="text-align: right;">Page 407</p> <p>1 BY MR. SLATER:</p> <p>2 Q. Strength of association,</p> <p>3 consistency, specificity, temporality,</p> <p>4 biologic gradient, plausibility,</p> <p>5 coherence, experimental evidence, and</p> <p>6 analogy, is that one way to describe</p> <p>7 those criteria?</p> <p>8 MR. PARKER: Objection.</p> <p>9 THE WITNESS: Yes, I believe</p> <p>10 so.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. And I'll actually -- counsel</p> <p>13 objected, so I'm going to read you -- I'm</p> <p>14 going to ask you a different question.</p> <p>15 With regard to the Bradford</p> <p>16 Hill criteria, I'm going to list what I</p> <p>17 believe to be some of those factors and</p> <p>18 -- well, actually, you know what? I</p> <p>19 don't need to go through it again.</p> <p>20 Are you familiar with the</p> <p>21 Bradford Hill criteria factors?</p> <p>22 A. Yes.</p> <p>23 Q. In analyzing, for example,</p> <p>24 the literature and your experience and</p>	<p style="text-align: right;">Page 409</p> <p>1 to you of any significance?</p> <p>2 MR. PARKER: Objection.</p> <p>3 MR. SLATER: You can answer.</p> <p>4 THE WITNESS: Okay. I don't</p> <p>5 think there's really any vagary to</p> <p>6 that statement. I think that</p> <p>7 they're expressly stating that</p> <p>8 this is a new category of patient</p> <p>9 that we're now aware of. I think</p> <p>10 that they're saying this</p> <p>11 information is important, to be</p> <p>12 widely distributed. And I</p> <p>13 absolutely agree.</p> <p>14 The patients that we've seen</p> <p>15 at Columbia who suffered from this</p> <p>16 condition have been in terrible</p> <p>17 shape. Many have had</p> <p>18 life-threatening illness. And</p> <p>19 there's a million</p> <p>20 antihypertensives on the market.</p> <p>21 I -- you know, very rarely do you</p> <p>22 see this degree of improvement,</p> <p>23 both pathologically and</p> <p>24 clinically, with a fairly simple</p>

<p style="text-align: right;">Page 410</p> <p>1 intervention.</p> <p>2 So I think that they were</p> <p>3 clearly stating that in their</p> <p>4 opinion, this is causal and a</p> <p>5 powerful intervention.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Do doctors recommend that</p> <p>8 patients be warned of a risk of taking a</p> <p>9 drug if they don't think the drug causes</p> <p>10 the risk?</p> <p>11 MR. PARKER: Objection.</p> <p>12 THE WITNESS: Could you</p> <p>13 repeat --</p> <p>14 MR. SLATER: Sure.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. This statement is</p> <p>17 recommending that patients be warned of</p> <p>18 the risk of what they call this</p> <p>19 complication.</p> <p>20 A. Uh-hum.</p> <p>21 Q. Would doctors make a</p> <p>22 recommendation that patients be warned of</p> <p>23 the risk of a complication with a drug if</p> <p>24 they didn't think the drug caused the</p>	<p style="text-align: right;">Page 412</p> <p>1 and methods, it states in part, "For</p> <p>2 inclusion into the study, the following</p> <p>3 criteria had to be met," and number 3 is</p> <p>4 exclusion of a medication-related</p> <p>5 etiology such as olmesartan or chronic</p> <p>6 nonsteroidal antiinflammatory drug</p> <p>7 (NSAID) use.</p> <p>8 Do you see what I just read?</p> <p>9 A. I do.</p> <p>10 Q. With regard to whether or</p> <p>11 not the authors of this study believe</p> <p>12 that olmesartan is a cause of an</p> <p>13 enteropathy that we're referring to as</p> <p>14 olmesartan enteropathy, those parts that</p> <p>15 I just read to you, what would be the</p> <p>16 significance of those sections I just</p> <p>17 read with regard to that question?</p> <p>18 MR. PARKER: Objection.</p> <p>19 THE WITNESS: Mind if I just</p> <p>20 take the (Indicating) --</p> <p>21 MR. SLATER: Yeah, sure,</p> <p>22 absolutely.</p> <p>23 THE WITNESS: Well, they say</p> <p>24 exclusion of a medication-related</p>
<p style="text-align: right;">Page 411</p> <p>1 complication?</p> <p>2 MR. PARKER: Objection.</p> <p>3 THE WITNESS: They would</p> <p>4 not.</p> <p>5 MR. SLATER: Now, I just</p> <p>6 have to find this one more</p> <p>7 article, and I think I left it on</p> <p>8 the desk, and then I'm done.</p> <p>9 (Pause.)</p> <p>10 BY MR. SLATER:</p> <p>11 Q. I'm looking at the</p> <p>12 Histopathology article that you were</p> <p>13 asked about by Brown, et al?</p> <p>14 A. Uh-huh.</p> <p>15 Q. And in the article, I'm</p> <p>16 looking at the -- page 255 and there's</p> <p>17 two things that they have: They have</p> <p>18 table 1 titled "Histological Mimics of</p> <p>19 Celiac Disease" and, if you go down, it</p> <p>20 says drugs, for example, NSAIDs,</p> <p>21 olmesartan, methotrexate, mycophenolate.</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. And then under the materials</p>	<p style="text-align: right;">Page 413</p> <p>1 etiology such as olmesartan, so to</p> <p>2 say that it's an etiology,</p> <p>3 etiology is cause, so I would</p> <p>4 interpret this to mean that the</p> <p>5 authors of this study believe that</p> <p>6 olmesartan causes enteropathy.</p> <p>7 MR. SLATER: Thank you.</p> <p>8 Depending on what Mr. Parker</p> <p>9 does in his inestimable wisdom --</p> <p>10 MR. PARKER: No, I believe</p> <p>11 the rules require me to limit my</p> <p>12 questions to your cross and</p> <p>13 there's nothing that was said that</p> <p>14 I have any other questions on.</p> <p>15 You're done.</p> <p>16 MR. SLATER: Thank you.</p> <p>17 (Witness excused.)</p> <p>18 (Deposition concluded at</p> <p>19 approximately 7:23 p.m.)</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p>1</p> <p>2 CERTIFICATE</p> <p>3</p> <p>4</p> <p>5 I HEREBY CERTIFY that the</p> <p>6 witness was duly sworn by me and that the</p> <p>7 deposition is a true record of the</p> <p>8 testimony given by the witness.</p> <p>9</p> <p>10 It was requested before</p> <p>11 completion of the deposition that the</p> <p>12 witness, STEPHEN M. LAGANA, M.D., have</p> <p>13 the opportunity to read and sign the</p> <p>14 deposition transcript.</p> <p>15</p> <p>16 KIMBERLY A. CAHILL, a</p> <p>17 Federally Approved Registered</p> <p>18 Merit Reporter and Notary Public</p> <p>19 Dated: February 9, 2017</p> <p>20</p> <p>21 (The foregoing certification</p> <p>22 of this transcript does not apply to any</p> <p>23 reproduction of the same by any means,</p> <p>24 unless under the direct control and/or</p> <p>supervision of the certifying reporter.)</p>	<p>1</p> <p>2 - - - - -</p> <p>3 E R R A T A</p> <p>4 - - - - -</p> <p>5 PAGE LINE CHANGE</p> <p>6 REASON: _____</p> <p>7</p> <p>8 REASON: _____</p> <p>9</p> <p>10 REASON: _____</p> <p>11</p> <p>12 REASON: _____</p> <p>13</p> <p>14 REASON: _____</p> <p>15</p> <p>16 REASON: _____</p> <p>17</p> <p>18 REASON: _____</p> <p>19</p> <p>20 REASON: _____</p> <p>21</p> <p>22 REASON: _____</p> <p>23</p> <p>24 REASON: _____</p>
<p>Page 415</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it.</p> <p>10 You are signing same subject</p> <p>11 to the changes you have noted on the</p> <p>12 errata sheet, which will be attached to</p> <p>13 your deposition.</p> <p>14 It is imperative that you</p> <p>15 return the original errata sheet to the</p> <p>16 deposing attorney within thirty (30) days</p> <p>17 of receipt of the deposition transcript</p> <p>18 by you. If you fail to do so, the</p> <p>19 deposition transcript may be deemed to be</p> <p>20 accurate and may be used in court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>Page 417</p> <p>1</p> <p>2 ACKNOWLEDGMENT OF DEPONENT</p> <p>3</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the</p> <p>6 foregoing pages, 1 - 418, and that the</p> <p>7 same is a correct transcription of the</p> <p>8 answers given by me to the questions</p> <p>9 therein propounded, except for the</p> <p>10 corrections or changes in form or</p> <p>11 substance, if any, noted in the attached</p> <p>12 Errata Sheet.</p> <p>13</p> <p>14</p> <p>15</p> <p>16 STEPHEN M. LAGANA, M.D. DATE _____</p> <p>17</p> <p>18</p> <p>19 Subscribed and sworn</p> <p>20 to before me this _____</p> <p>21 day of _____, 20____.</p> <p>22 My commission expires: _____</p> <p>23</p> <p>24 Notary Public</p>

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